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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,880	12/12/2003	John P. Fruehauf	02-1270-A	1031

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Chicago, IL 60606

EXAMINER
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YAO, LEI

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/734,880

Applicant(s)

FRUEHAUF, JOHN P.

Examiner

Lei Yao, Ph.D.

Art Unit

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The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Reply

SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS,  
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed  
after SIX (6) MONTHS from the mailing date of this communication.

If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  
Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any  
earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is  
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.  
4a) Of the above claim(s) 1-19, 22-39 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 20 and 21 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage  
application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of Group VIII (claims 20-21) in the reply filed on 3/0/06 is acknowledged.

Applicant requests to examine the Group VIII and IX together because the Office action dated 10/4/05 does not set forth reasonable basis that these claims can not be examined together and there is not undue burden on the search of two group together.

These have been considered, but not found persuasive. As discussed in the restriction requirement (10/4/05) and also stated in MPEP, inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Although both groups are drawn to method of identifying tumor cells by determining the gene expression of one or more genes, two methods are involved in different cell populations (drug sensitive and resistant cells), which may express different genes. The genes expressed in sensitive cells may not be all expressed in the resistant cells and the genes expressed in resistant cells may not be expressed in the sensitive cells. Searching two methods are not co-extensive in non-patent literature and US patent database, which would impose a serious search burden. For this reason, the restriction requirement is deemed to be proper and is adhered to. The requirement is therefore made **FINAL**.

Claims 1-39 are pending. Claims 1-19 and 22-39 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention and species. Claims 20-21 are examined on the merits.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mechetner et al., (Clinical Cancer Research, vol 4, page 389-398, 1998) as evidenced by Sharom F (J Bioenerg Biomembr, vol 27, page 15-22, abstract) and Gottesman et al., (Nature review, col 2, page 48-58, 2002).

The set of claims is drawn to a method for identifying cells or a tumor comprising breast cancer that are resistant to taxane chemotherapeutic drugs comprising steps of determining and comparing the expression of ATPase gene and identifying the tumor or cells by increased the expression of the gene in the resistant cells.

Mechetner et al., disclose a method for identifying of a tumor and cells resistant to Taxol, a taxane chemotherapeutic drug, by increased P-glycoprotein (Pgp) expression in human breast cancer cells. P-glycoprotein is ATP transporter protein having ATPase activity as evidenced by Sharom F (line 13-15) and Gottesman et al., (page 49, col 3, para 2, to page 50). Mechetner et al., disclose that Pgp expression in the samples is determined by flow cytometry or immunohistochemistry (p 391, col 1). Mechetner et al., also disclose the comparison and quantization of Pgp expression in the clinical specimen of breast carcinoma from the patients treated and untreated with Taxol (p 393, col 2, last para and table 2). Mechetner et al., disclose that higher levels of Pgp expression in the samples resistant to Taxol and that the degree of Pgp expression strongly correlated with the degree of drug resistance in the clinical specimen studies (fig 3, page 395 and page 394, col 1, para 3). Mechetner et al., further disclose the degree of expression of Pgp in breast cancer will significantly contribute to the levels of clinical resistance to Taxol (p 396, col 1, last para).

2. Claims 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Junkun et al., (J Cell Biochem, vol 53, page 135-144, 1993) or Jankun et al., (US Patent 5679350, 1997) as evidenced by Mesh word search in NCBI (exhibit A).

The claim 20 is drawn to a method for identifying a tumor or tumor cells comprising determining and comparing gene expression of Urokinase receptor and identifying the tumor or tumor cells by

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increased the expression of the gene in the tumor cells. Claim 21 is further drawn to claim 20, wherein tumor sample is breast cancer samples.

Junkun et al., (JCB) disclose a method for identifying a tumor cells by the levels of expressing Urokinase plasminogen activator receptor (uPAR), alternative name of Urokinase receptor as evidenced by Mesh word search in NCBI (exhibit A), expression on tumor cells. Junkun et al., disclose that the method comprise comparing Urokinase receptor expressed on breast cancer tissue cells to normal breast tissue using immunohistochemical staining (page 137, col 2 to page 138 and figure 2). Junkun et al., further disclose that malignant tumors express higher levels (intensive staining) of uPAR than the normal breast tissues (page 137, col 2)

Jankun et al., (Patent 5679350) disclose a method of identifying tumor cells by the levels of Urokinase plasminogen activator receptor (uPAR) expressed on breast cancer tissues to normal breast tissue by immunohistochemical staining. Jankun et al., disclose that uPAR is highly expressed on the breast tumor compared to normal breast tissues (col 11, line 65- col 13).

3. Claim 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Gong et al., (Dev Biol, vol 183, page 166-82, 1997).

The claim 20 is drawn to a method for identifying a tumor or tumor cells comprising determining gene expression of HIP116 gene and identifying the tumor or cells by increased the expression of the gene in the tumor cells.

Gong et al., disclose a method for identifying tumor cells comprising determining the expression of Zbul gene (HIP116, abstract, line 3) in tumor cells. Gong et al., disclose that HIP116 gene expression is dramatically induced in human tumor lines (abstract, line 10, figure 4 on page 170).

### ***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.  
Examiner  
Art Unit 1642

LY

*Sheela Huff*  
SHEELA HUFF  
PRIMARY EXAMINER